

Figure 1

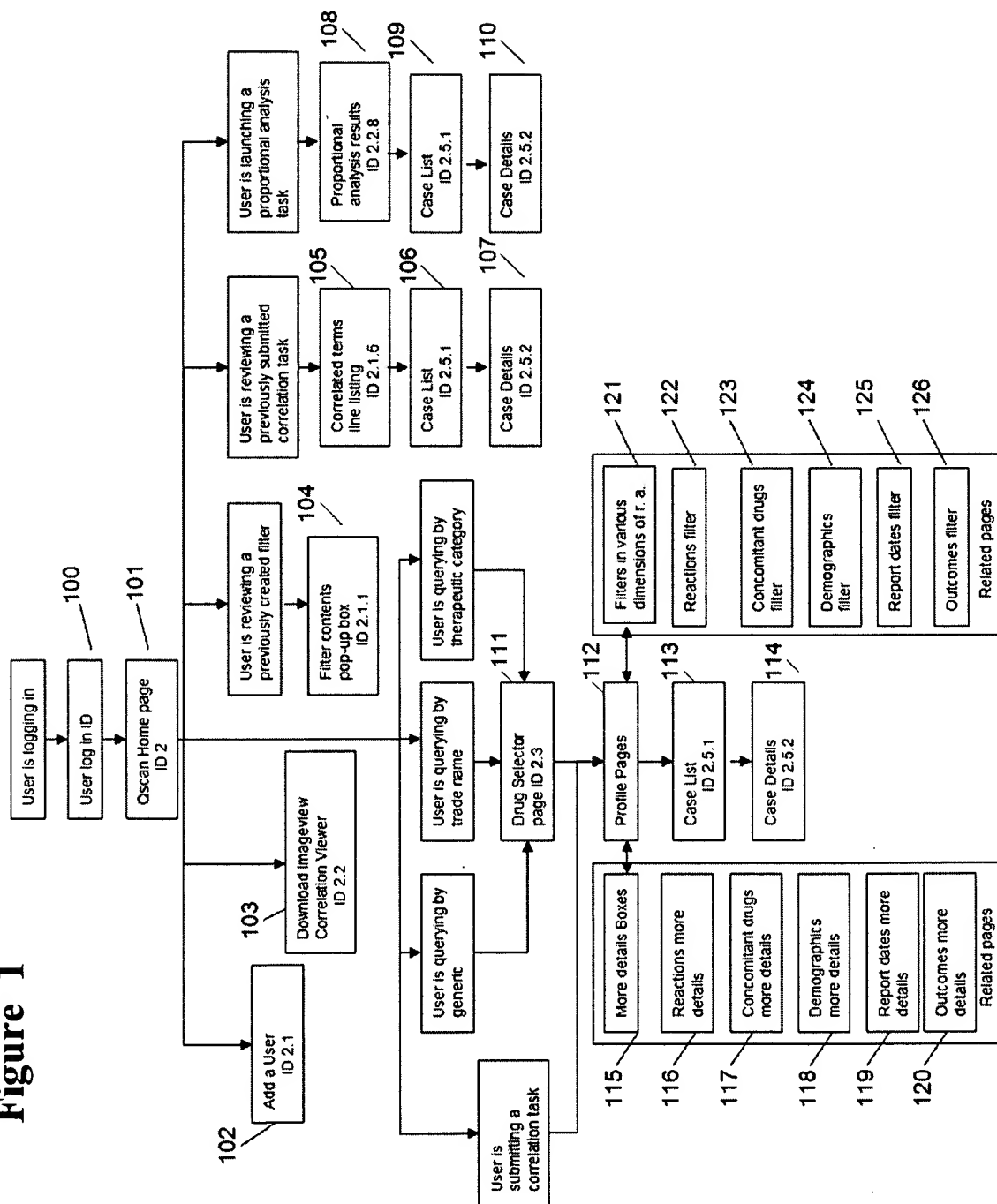


Figure 2

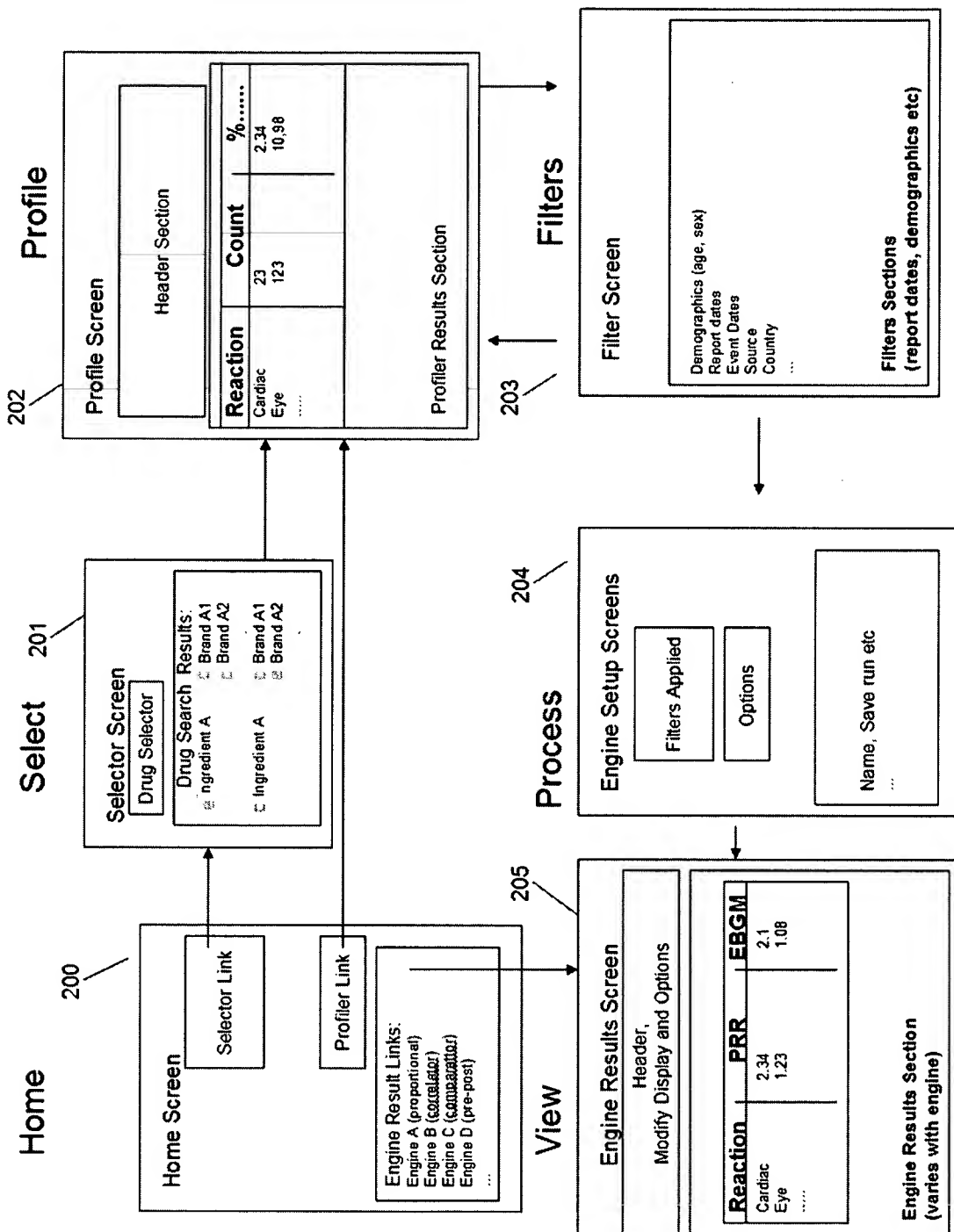


Figure 3

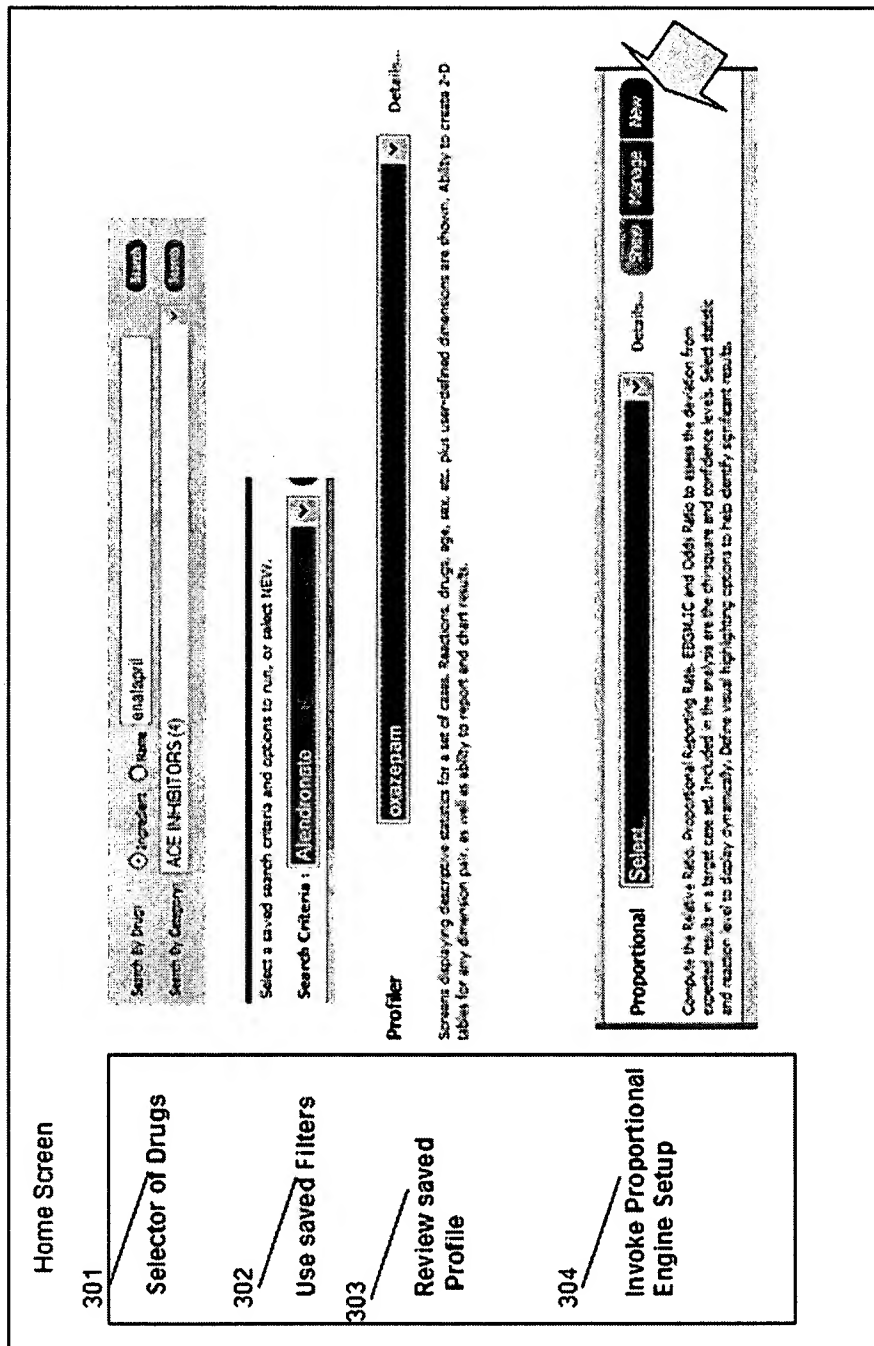


Figure 4

Filter Screen

401	Summary	Search Criteria Details	
400	Drugs (details)	Search Criteria Items: Alendronate 396	(Drug Legend: A=All, S=Subset, I=Ingredient, R=Drug Name)
402	Reactions (details)	Criteria	Value
403	Demographics	Included Ingredients	ALENDRONATE SODIUM (A)
404	Report Dates	Drug boolean	((ALENDRONATE SODIUM)) [DO NOT MATCH OFF]
	Event Dates	Reactions	si[INCLUDED]
	Outcomes	Demographics	si
	Report Sources	Report Dates	From Feb 1, 1999 To: Mar 6, 1999
	Report Types	Event Dates	si
	Case Sources	Included Outcomes	CONGENITAL ANOMALY, DEATH, DISABILITY
	Excluded Cases	Report Sources	si
	Excluded Duplicate Cases	Report Types	si
	Notes	Case Sources	si
		Excluded Cases	none
		Excluded Duplicate Cases	off

Figure 5

Query Screen

503

500 (Generic, or 'ingredient')

501 (Trade name)

Search By Drug

☐ Ingredient ☐ Name

Search By Category

ACE INHIBITORS (4)

4 trade(s) matched

Ingredients (all suspect)	Names (Show all names)
ENALAPRIL MALEATE (1, 0)	<input type="checkbox"/> ENALAPRIL MALEATE TABLETS (1, 0)
LOSINOAPRIL (13, 6)	<input type="checkbox"/> LOSINOAPRIL TABLETS (12, 6) <input type="checkbox"/> ORINTIV TABLETS (1, 0)
HYDROCHLOROTHIAZIDE TELMSARTAN (0, 0)	<input type="checkbox"/> MICARDIS HCT TABLETS (4, 0)

To view drug list and  
define logical rules, click  
Detailed Setup

No. of Ingredients Searched  
0

No. of Drugs Searched  
0

Review Selection and Set  
Detailed Options  
Detailed Setup

Figure 6

DATA PEDIGREE Screen							
600	601	602	603	604	605	606	607
MAPTO	VERBATIM	SOURCE	INCIDENTS	CASE COUNTS	PROCESSING	Cross reference	FIRST/LAST
PROZAC	PROZAC	SRS	17933	17933	A	Orange Book	1/27/69 - 12/2/97
PROZAC	PROZAC	AERS	3309	3309	A	Orange Book	11/1/89 - 6/2/99
PROZAC	PROZAC (SUOX)	AERS	2	2	M	NDCD	2/27/69 - 2/2/97
FLUOXETINE	FLUOXETINE HCL	AERS	122	122	M	Orange Book	6/27/69 - 1/2/97
ETC....							

Figure 7

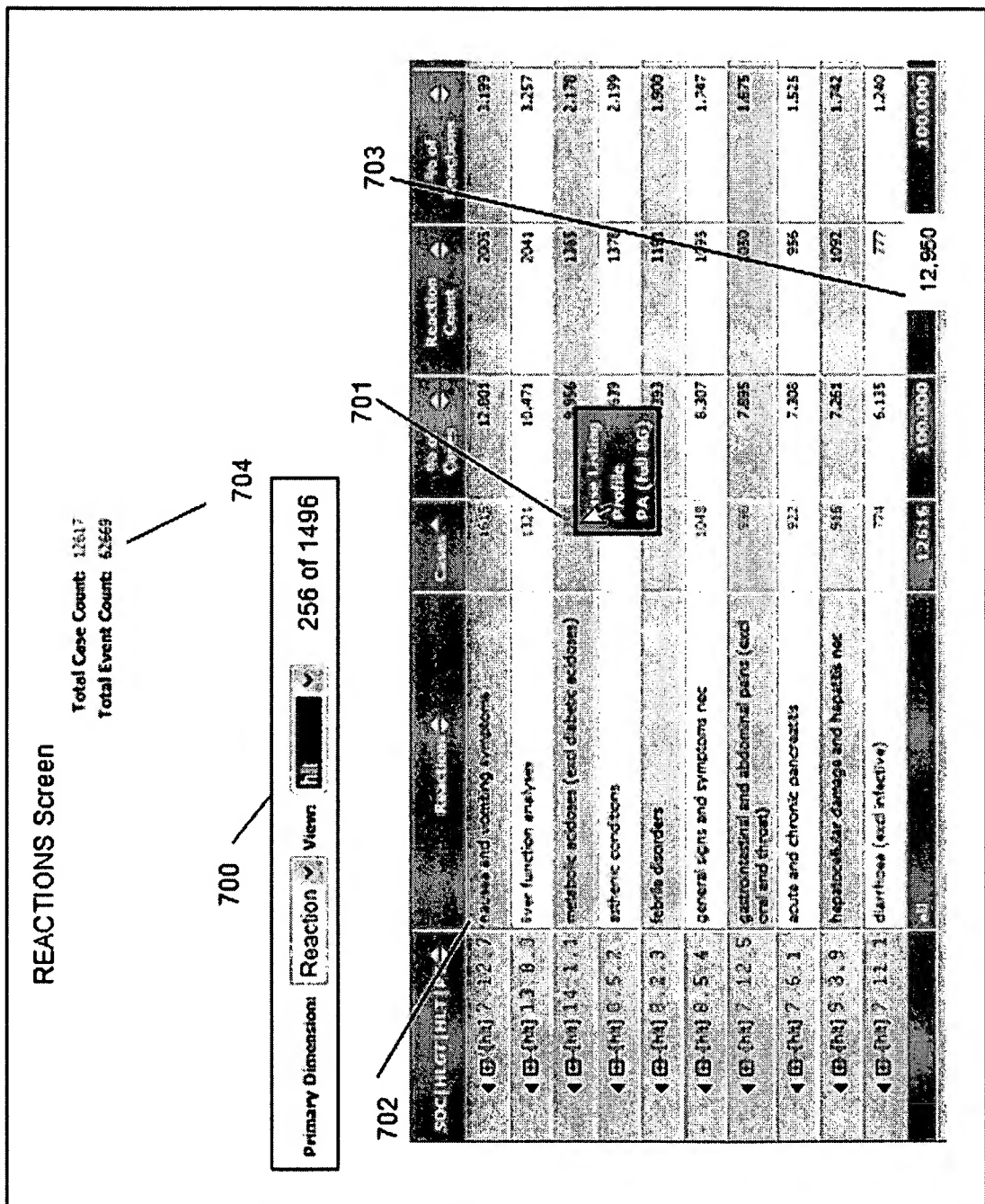


Figure 8

**DRUGS Screen**

Total Case Count: 15617

Primary Dimension: Drugs View: Ingredients

800	Drugs	Cases	Qty of Cases	801	802
	<input type="checkbox"/> STAYLONE	1287	150,000	555	535
	<input type="checkbox"/> LAMOTRIGINE	731	61,274	423	395
	<input type="checkbox"/> DEBACOSIDE	150	25,777	302	162
	<input type="checkbox"/> RINDIVAB SULFATE	824	18,541	798	65
	<input type="checkbox"/> RITONAVIR	379	18,147	308	408
	<input type="checkbox"/> SALAFETHANOL	707	21,076	491	264
	<input type="checkbox"/> TURETHOTIN	204	22,577	400	240
	<input type="checkbox"/> HELFNAVE MEDICATE	242	19,355	170	61
	<input type="checkbox"/> NEVIRAPINE	218	18,372	150	43
	<input type="checkbox"/> EFANBENZ	146	17,029	163	152
		15617	100,000	3460	4319



## Figure 12

Reaction Filter Screen

Find Reactions

Collapse Reaction Tree

Detailed Setup

Search Reactions

Reactions

☒ [SOG] blood and lymphatic system disorders

☒ [HLGT] anemias nonhemolytic and marrow depression

☒ [HLGT] bleeding tendencies and purpura (excl thrombotic/thrombotic)

☒ [HLT] bleeding tendencies

☐ [PT] bleeding tendency

☐ [PT] haemorrhagic disease of newborn

☒ [PT] haemorrhagic disorder

☒ [HLT] purpura (excl thrombotic/thrombotic)

☒ [HLGT] coagulopathies and bleeding diatheses

☒ [HLGT] haematological disorders nec

☒ [HLGT] haematopoietic neoplasms (excl leukemias and lymphomas)

☒ [HLGT] haemoglobinopathies

☒ [HLGT] haemolysis and related conditions

☒ [HLGT] leukaemias

☒ [HLGT] platelet disorders

☒ [HLGT] red blood cell disorders

☒ [HLGT] spleen, lymphatic and reticuloendothelial system disorders

☒ [HLGT] white blood cell disorders

☒ [SOG] cardiac disorders

☒ [SOG] congenital, familial and genetic disorders

## Figure 13

Box	Category	Term 1	Term 2	Category	Score	Care Counts	DF	Confidence Level	Rank
<input type="checkbox"/> CANDESARTAN CILEXETIL							12317364	99.99	1
<input type="checkbox"/> Sex							12317364	99.99	14
Female	Drugs	CANDESARTAN CILEXETIL	Female	Sex			12317364	99.99	234
Male	Drugs	CANDESARTAN CILEXETIL	Male	Sex			9753666	99.98	...
Sex Not Specified	Drugs	CANDESARTAN CILEXETIL	Sex Not Specified	Sex	0.2222		1142103	99.96	2
<input type="checkbox"/> Demographics							13004129	99.99	23
Age 51 to 75 Years	Drugs	CANDESARTAN CILEXETIL	Age 51 to 75 Years	Demographics			12004129	99.99	45
Age over 75 Years	Drugs	CANDESARTAN CILEXETIL	Age over 75 Years	Demographics	0.4591		4891265	99.97	67
Age Not Specified	Drugs	CANDESARTAN CILEXETIL	Age Not Specified	Demographics	0.3966		3666135	99.97	
Age 31 to 50 Years	Drugs	CANDESARTAN CILEXETIL	Age 31 to 50 Years	Demographics	0.3343		2438414	99.97	

Figure 14

Correlation Case List Details Screen

Case ID	Sex	Medical Record Control Code	FOIA Request Receipt Date	Age	Drug	Reactions	Outcomes	Reporting Country	Tracking
485409	U	50034400355	2003/03/14	9	ATACAND	convulsions nos. drug exposure via breast milk	REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE		<input checked="" type="checkbox"/>
494609	M	20040726149	2005/01/03	0	ATACAND, HYDROCHLOROTHIAZIDE, SYNTHROID	drug exposure during pregnancy, foetofetal toxicity, jaundice, neonatal oligohydramnios, ultrasound antenatal screen abnormal, ultrasound kidney abnormal	REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE		<input checked="" type="checkbox"/>
3041306	F	20000900273	2001/01/02	14	ATACAND, ATACAND	nil discoloration, tooth discoloration, tremor	OTHER		<input checked="" type="checkbox"/>
376447	M	20010405707	2001/07/06	2	ATACAND	accidental exposure	OTHER		<input checked="" type="checkbox"/>
502236	M	JP-ROOHE-17925	2004/12/09	9	ROCEPHIN, FAMIOTIDINE, DILTIAZEM, CLARITHROMYCIN, COMELIAN, BLOPRESS, URSO	choleystasis chronic nos. cholelithiasis	OTHER		<input checked="" type="checkbox"/>
475402	M	20030500411	2003/02/13	14	BLOPRESS	hemodistasis, renal failure acute	HOSPITALIZATION INITIAL OR		<input checked="" type="checkbox"/>

Figure 15

Case Details Screen														
1501	Case ID:	J41206												
1502	Sex:	F												
1503	Age:	11 years 0 months												
1504	Weight:	None												
	Death Date:	None												
	Readings:	As Reported	Onset Date	Preferred Term	High Level Term	High Level Group Term	System Organ Class							
		Self Discontinuation	—	self discontinuation	red and nail bed conditions (and infections and irritations)	skin appendage conditions	skin and subcutaneous tissue disorder							
		Tooth Discoloration	—	tooth discoloration	dermal surface disorders	dental and gingival conditions	gastrointestinal disorders							
		Tumor Rec	—	tumor	tumor (viral congenital)	movement disorders (incl. parosmia)	neurological disorders							
1505	Concomitant Drugs:	As Reported	Name	Dose	Route	Drug Role	Dechallenge	Rechallenge	Therapy Started Date	Therapy Stopped Date	Days Therapy Duration	Days to Onset	Indication	Lot Number
		Alized	ATACAND	15 MG QD	PO	Primary Suspect Drug	Positive dechallenge	Does not apply	03 Aug 2000	—	—	—	—	—
		Alized	ATACAND	15 MG QD	PO	Secondary Suspect Drug	Positive dechallenge	Does not apply	03 Apr 1999	03 Aug 2000	—	—	—	—
1506	Outcome:	OTHER(OT)												
1509	Event Date:	None												
1507	Sending Manufacturer:	AstraZeneca Pharmaceuticals LP												
1508	Manufacturer Control Code:	2800000073												
1510	Manufacturer Date:	12 Sep 2000												
1511	Report Code:	Periodic												
1512	Report Source:	Health Professional												
1513	Case Source:	None												



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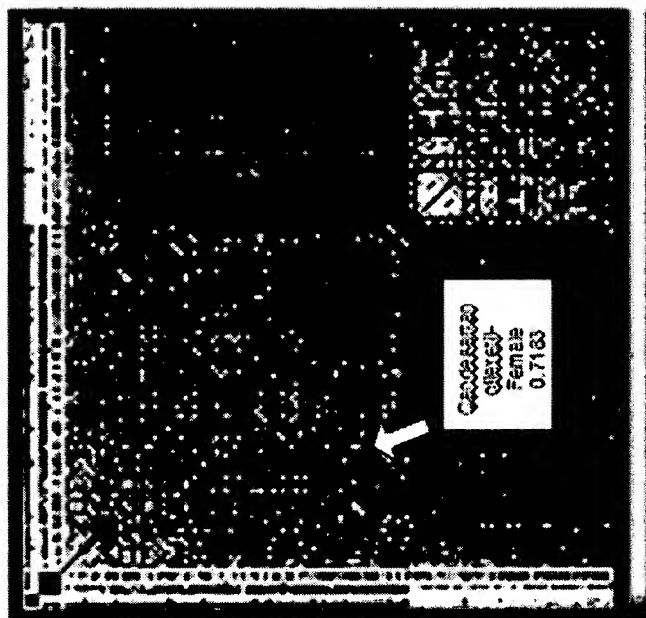
Figure 16

Correlator Display Screens

Column Display

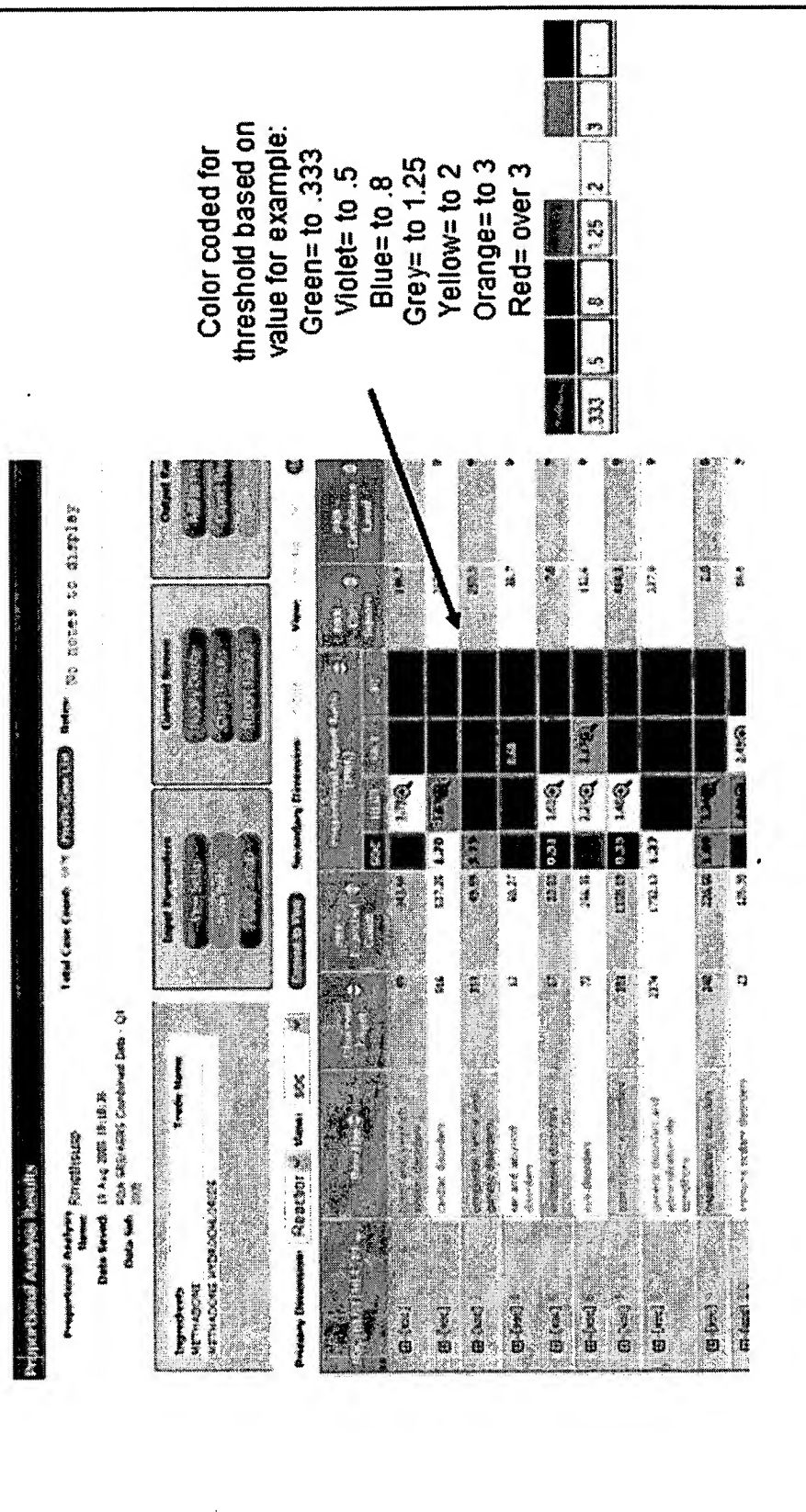
"radar" Display (Color for Score)

Drug	Category	Temp	Temp	Temp	Temp
1. CANNABIS	Drug	1. CANNABIS	1. CANNABIS	1. CANNABIS	1. CANNABIS
2. CANNABIS	Drug	2. CANNABIS	2. CANNABIS	2. CANNABIS	2. CANNABIS
3. CANNABIS	Drug	3. CANNABIS	3. CANNABIS	3. CANNABIS	3. CANNABIS
4. CANNABIS	Drug	4. CANNABIS	4. CANNABIS	4. CANNABIS	4. CANNABIS
5. CANNABIS	Drug	5. CANNABIS	5. CANNABIS	5. CANNABIS	5. CANNABIS
6. CANNABIS	Drug	6. CANNABIS	6. CANNABIS	6. CANNABIS	6. CANNABIS
7. CANNABIS	Drug	7. CANNABIS	7. CANNABIS	7. CANNABIS	7. CANNABIS
8. CANNABIS	Drug	8. CANNABIS	8. CANNABIS	8. CANNABIS	8. CANNABIS
9. CANNABIS	Drug	9. CANNABIS	9. CANNABIS	9. CANNABIS	9. CANNABIS
10. CANNABIS	Drug	10. CANNABIS	10. CANNABIS	10. CANNABIS	10. CANNABIS
11. CANNABIS	Drug	11. CANNABIS	11. CANNABIS	11. CANNABIS	11. CANNABIS
12. CANNABIS	Drug	12. CANNABIS	12. CANNABIS	12. CANNABIS	12. CANNABIS
13. CANNABIS	Drug	13. CANNABIS	13. CANNABIS	13. CANNABIS	13. CANNABIS
14. CANNABIS	Drug	14. CANNABIS	14. CANNABIS	14. CANNABIS	14. CANNABIS
15. CANNABIS	Drug	15. CANNABIS	15. CANNABIS	15. CANNABIS	15. CANNABIS
16. CANNABIS	Drug	16. CANNABIS	16. CANNABIS	16. CANNABIS	16. CANNABIS
17. CANNABIS	Drug	17. CANNABIS	17. CANNABIS	17. CANNABIS	17. CANNABIS
18. CANNABIS	Drug	18. CANNABIS	18. CANNABIS	18. CANNABIS	18. CANNABIS
19. CANNABIS	Drug	19. CANNABIS	19. CANNABIS	19. CANNABIS	19. CANNABIS
20. CANNABIS	Drug	20. CANNABIS	20. CANNABIS	20. CANNABIS	20. CANNABIS



## Figure 17

### Proportional Display Screen: Matrix



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Figure 18

Proportional Display Screen: Detail	
1800 —	Drug
1801 —	Reaction
1802 —	Reaction Count
1803 —	Expected Reaction Count
1804 —	Relative Rate
AMLODIPINE BESYLATE	
Surgical and medical procedures	
	927
	201.02
	4.61

Figure 19

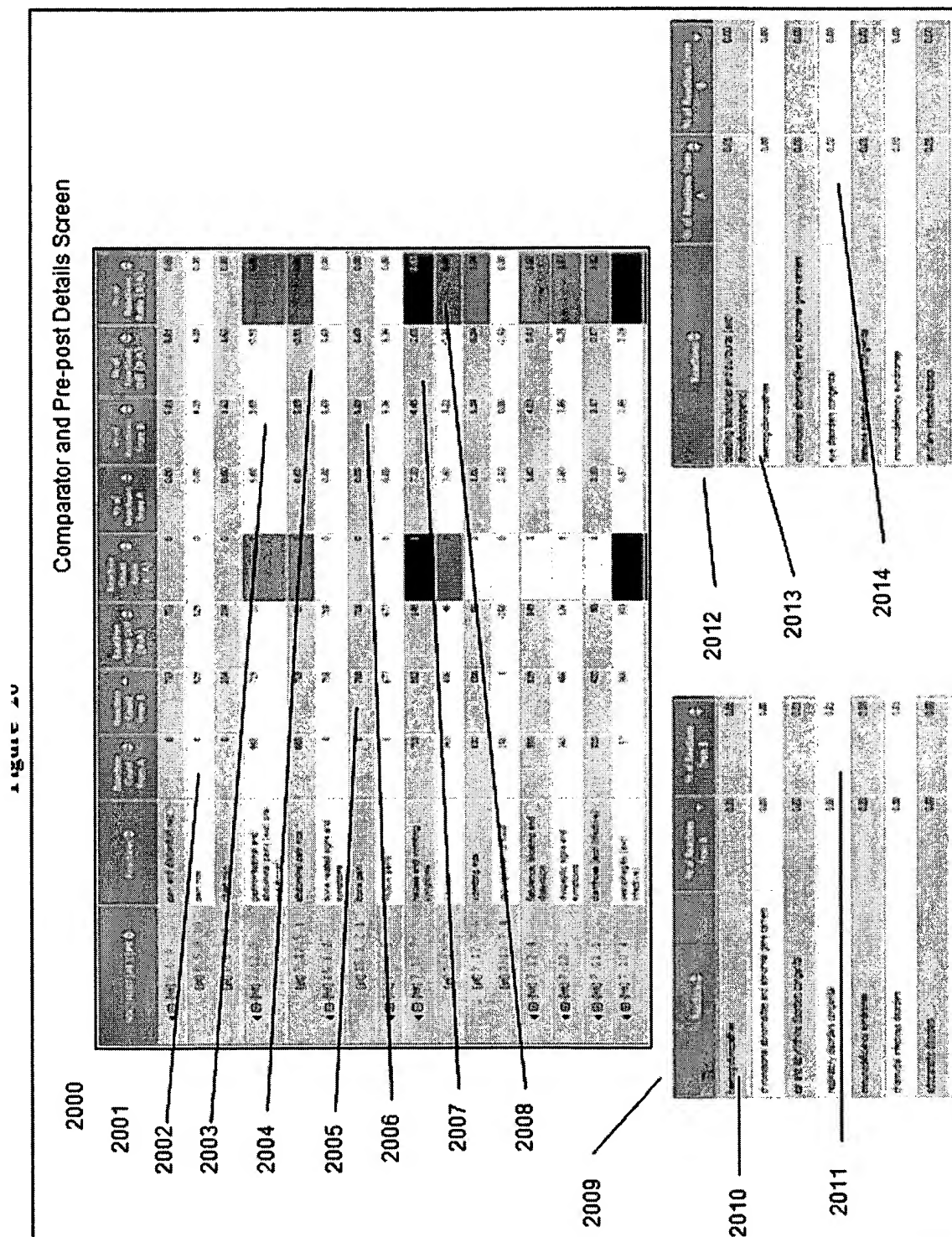
Proportional Display Screen: line

1901	1900	1902	1903	1904
Drug	Reaction	Events	RR Expected Count	Relative Risk (RR)
		5000	0.00	
		5000	0.00	
ASACAVIR SULFATE	blood and lymphatic system disorders	11	12.14	0.61
ABECIMAB	blood and lymphatic system disorders	100	44.25	
ACARBOSE	blood and lymphatic system disorders	25	5.91	2.52
ACEBUTOLOL HYDROCHLORIDE	blood and lymphatic system disorders	12	10.75	1.12



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## Figure 20



## Figure 21

[illegible]